

- (ii) a Raman spectrum containing peaks at 1762, 1284, 912 and 888 cm<sup>-1</sup>;
- (iii) a solid-state <sup>13</sup>C nuclear magnetic resonance spectrum containing peaks at 111.0, 113.6, 119.8, 129.1, 130.9, 131.8, 134.7, 138.7, 146.5, 152.7, 157.5, 169.5, 171.0, 178.7 ppm; or
- (iv) an X-ray powder diffraction (XRPD) pattern having calculated lattice spacings at 5.87, 5.30, 4.69, 4.09, 3.88, 3.61, 3.53 and 3.46 Angstroms.

16. (New) A polymorph according to claim 15 which has an infra red spectrum substantially in accordance with Figure I.

17. (New) A polymorph according to claim 15 which has a Raman spectrum substantially in accordance with Figure II.

18. (New) A polymorph according to claim 15 which has a solid-state <sup>13</sup>C nuclear magnetic resonance spectrum substantially in accordance with Figure III.

19. (New) A polymorph according to claim 15 which has a solid-state <sup>13</sup>C nuclear magnetic resonance spectrum substantially in accordance with Table I.

20. (New) A polymorph according to claim 15 which has an X-ray powder diffraction pattern substantially in accordance with Figure IV.

21. (New) A polymorph according to claim 15 which has an X-ray powder diffraction pattern substantially in accordance with Table II.

22. (New) A polymorph according to claim 15 in isolated form.

23. (New) A polymorph according to claim 15 in pure form.

24. (New) A polymorph according to claim 15 in crystalline form.

25. (New) A process for preparing the polymorph according to claim 15, comprising:

suspending 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl] thiazolidine-2,4-dione, maleic acid salt in acetone; stirring the suspension at an elevated temperature for an extended period of time; and recovering the polymorph.

26. (New) A process for preparing the polymorph according to claim 15, comprising:

seeding a solution of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl] thiazolidine-2,4-dione, maleic acid salt in denatured ethanol at an elevated temperature with crystals of the polymorph; cooling the seeded solution; and recovering the polymorph from the denatured ethanol.

27. (New) A pharmaceutical composition comprising an effective, non-toxic amount of the polymorph according to claim 15 and a pharmaceutically acceptable carrier therefor.

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*Cont.*

28. (New) A method for the treatment or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, in a human or non-human mammal which comprises administering an effective, non-toxic, amount of the polymorph according to claim 15 to a human or non-human mammal in need thereof.

29. (New) A method for the treatment of Type II diabetes in a human comprising administering an effective, non-toxic amount of the polymorph according to claim 15 to a human in need thereof.

30. (New) A method of claim 29, wherein the administrating comprises oral administration.

31. (New) A method of claim 30, wherein the polymorph is administered in the form of a tablet or capsule for said oral administration.

32. (New) A composition according to claim 27 which is adapted for oral administration.

33. (New) A composition according to claim 32 which is in the form of a table or a capsule for said oral administration.

34. (New) A polymorph which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said polymorph has:

- (i) an infra red spectrum containing peaks at 1763, 912, 856 and 709 cm<sup>-1</sup>;  
(ii) a Raman spectrum containing peaks at 1762, 1284, 912 and 888 cm<sup>-1</sup>;  
(iii) a solid-state <sup>13</sup>C nuclear magnetic resonance spectrum containing peaks at 111.0, 113.6, 119.8, 129.1, 130.9, 131.8, 134.7, 138.7, 146.5, 152.7, 157.5, 169.5, 171.0, 178.7 ppm; and  
(iv) an X-ray powder diffraction (XRPD) pattern having calculated lattice spacings at 5.87, 5.30, 4.69, 4.09, 3.88, 3.61, 3.53 and 3.46 Angstroms.

REMARKS

The claims are 15-34 with claims 15 and 34 being independent. Support for claims 15-28 and 34 may be found in original claims 1-10 and 14. Support for claim 29 may be found in the specification at page 3, line 4. Support for claims 30-33 may be found in the specification at page 3, line 32 to page 4, line 9. No new matter has been added.

Although no official action has been taken regarding new claims 15-34, these claims define the same subject matter and contain many of the same terms as original claims 1-10 and 14 that were examined and were the subject of the Office Action dated September 10, 2002. To expedite prosecution of the subject application, Applicants will address the objections raised in the Office Action to the extent that they pertain to the new claims. Applicants respectfully traverse the rejections in the Office Action.

The Examiner had objected to original claims 2-5 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting the limitation of a figure or a table. Applicants respectfully submit that claims 16-21 are written in accordance with M.P.E.P. 2173.05(s). Claims that are written to incorporate by reference a specific figure or table are permitted and are not considered indefinite.